IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Attorney Docket No. 112280.121US3

Applicants:	Opolski, M.	Examiner:	Reddick, J.
Filed:	May 15, 2001	Art Unit:	1713
Serial No.:	09/855,923		
Entitled:	Water-Based Hydrophilic Compositions and Articles Prepared Therefrom		

CERTIFICATION UNDER 37 CFR § 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Arlington, VA 22313-1450 on the date indicated below.

May 20, 2003
Date of Signature and of Mail Deposit

J. Dean Farmer, Jr.

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

DECLARATION OF MARGARET P. OPOLSKI UNDER 37 CFR §1.132

Under 37 CFR §1.132 and regarding the rejection of the pending claims over U.S. Patent 5,272,012, I declare:

1. I am an inventor of the subject matter described and claimed in the above-captioned patent application and in the cited reference U.S. Patent 5,272,012 (the "Opolski patent").

2. I have been working in the field of polymer coatings and adhesives for 28 years and in particular their use with medical devices for at least 15 years. My *curriculum vitae* is attached as Exhibit 1. In particular, I note that I was employed by the Permuthane Division of ICI/Zeneca, a supplier of polymer resins such as those used in the Oploski patent.

3. I have read and understood the office action dated December 20, 2002. This Declaration is made in order to respond to the 35 USC § 102 rejection of the claims over the Opolski patent. The Examiner has asserted that one of ordinary skill in the art would have readily envisioned the use of a lactam such as polyvinylpyrrolidone *in lieu* of or in addition to dimethyl siloxane in the acrylic polymer coatings described in the Opolski patent. This declaration is made to provide information regarding siloxanes used as slip additives in the Opolski patent and to establish the incompatibility of polyvinylpyrrolidone polymers as a substitute therefore.

4. Opolski teaches that a siloxane is dispersed in an acrylic resin to form a siloxane/acrylic emulsion. Upon coating an article with this siloxane/acrylic emulsion, the siloxane is contained within pockets, *i.e.*, micelles, dispersed discontinuously within the coating. The siloxane exists in distinct domains within the protective polymer (film) that then migrate through the film to the surface, thereby providing slip to the coated article. The inherent *hydrophobic* properties of the siloxane cause the siloxane to remain within the protective polymeric film for as long as possible, thereby increasing its residency time in the film and reducing the rate at which the siloxane is removed from the coating out into the aqueous environment.

5. Opolski further teaches the use of polyvinylpyrrolidone (PVP) copolymer as a slip additive that attempts to mimic the discontinuous, domain forming properties of the siloxanes. However, the PVP copolymer does not readily segregate into distinct, discontinuous domains due to the inherent hydrophilic (water loving) property of the copolymer. According to Opolski the PVP copolymer is covalently attached to the coating, causing it to be localized in a region of the coating, in a manner similar to the discrete domains observed for siloxane. An example of PVP *copolymer* employed in Opolski as a slip additive is PVP-13.30q (ACP-1005), which was obtained from GAF Chemicals (a division of International Specialty Products (ISP)). The enclosed product literature ((ACP-1033) attached as Exhibit 2) was provided to me by ISP and demonstrates that a PVP copolymer of the type disclosed in the Opolski patent is a PVP *copolymer* with acrylic acid (AA). In the presence of aziridine and under the reaction conditions used to form a coated article, the acrylic acid-containing copolymer will react with aziridine to form bridging links (crosslinks) to the functional groups of the protective polymer (or substrate).

Thus, the resultant composition includes PVP/AA *copolymer* covalently bound to the protective polymer. This covalent crosslinking of the PVP/AA slip additive to the protective polymer hinders the slip additive from leaching from the film into the aqueous environment.[1]

6. In contrast, a PVP *polymer*, which has no functional moieties, is not crosslinkable to the protective polymer of Opolski and therefore readily leaches out of the film into the aqueous environment and therefore confers no sustained slip property to the coating without the crosslinked property disclosed and claimed in the current application. The use of such a polymer is not suggested anywhere in the Opolski patent.

7. In conclusion, Opolski teaches that in order to confer slip to a coated article, a hydrophobic slip additive such as siloxane can be added to a protective polymer. The hydrophobic property of the siloxane slip additive causes it to exist as distinct, discontinuous domains within the film. Opolski further teaches that hydrophilic polymers such as PVP copolymers can also be used as slip additives by crosslinking the copolymer to the protective polymer or to the surface of the article being coated, so as to localize the slip additive within a region of the protective polymer and hinder the slip additive from leaching out into the aqueous environment. The present application is directed to a novel method for conferring slip to a coated article. By determining the appropriate crosslink density of the supporting polymer, a hydrophilic polymer such as a PVP polymer can be entrapped within the supporting acrylic polymer without covalent attachment to the supporting polymer or to the article, thereby hindering the leaching of the hydrophilic polymer that provides the slip into the aqueous environment.

8. For the foregoing reasons, it is my opinion that the Opolski patent does not teach or suggest the substitutability of PVP for siloxanes in the coating composition of the Opolski patent. The Opolski patent recognizes the fundamental differences between a hydrophobic slip additive such as siloxanes, and hydrophilic polymers such as PVP. Recognizing those differences, the Opolski patent suggests the use of crosslinkable polymers as the hydrophilic slip additive. Therefore, Opolski does not teach the invention claimed in the present application.

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[1] Of note, a polymer coating including an acrylic supporting polymer and a PVP/AA slip additive was manufactured and found not to be particularly successful in conferring lubriciousness to the coated article.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patents issued thereon.

Date: 5/20/03

Margaret P. Opolski

Exhibit 1

Principal **Margaret Palmer Op Iski**

An innovative chemical professional with extensive applications, technical and managerial experience in medical, automotive,textile and industrial coatings and adhesives. Specific skills and abilities:

* Chemical Problem solving skills customizing water-based and urethane coatings and adhesives.
* Proactive analytical abilities determining organizational needs and meeting them.
* Technical leadership hiring, coaching and developing technical professionals
* Effective communications in teaching, sales training, technical marketing with some Spanish.

Pr fessional Experience

Surface Solutions Laboratories, Inc - Carlisle, MA

President

Founded and incorporated a business for the development of custom, water-based, medical device coatings and adhesives. Patents issued for protective coating(currently licensed for stent-delivery balloons), hydrophilic coating applied from water (currently licensed to AST as LubrilAST), and sustained release coatings under development for various medical and industrial applications. Patent draft for slip coating for inner surfaces. Non-mercury, non-aqueous conductive liquid patent pending.,conductive, Drug delivery,antithrombogenic, anticorrosion, antimicrobial, laser-markable, dielectric and radiopaque coating development in progress. Custom development upon request.

Gel Sciences, Inc. Bedford, MA

Senior Scientist/Consultant

Venture start-up utilizing lyogel and hydrogel technologies for reactive chemistry delivery and catalysis. Patent pending technology for encapsulation and subsequent release of a variety of chemicals.

USCI Division of C.R. Bard- Billerica, MA

Staff Engineer, Research

Product development for hydrophilic coating for approximately $30 million of stainless steel and other guidewire business. Interface with Dupont on coatings issues and represented USCI division for coating activities. Delivered presentations on sensitive coating technical matters to Dupont and ICI/Zeneca.

Staff Engineer, Manufacturing

Technical support for the manufacturing issues and technology portfolio in guidewires and catheters. Converted CFC usage for $500,000 cost savings.

Engineering Section Head, Research and Development

Coordinated the activities of 9 internal consultants to USCI and all Bard divisions for polymers, coatings, metallurgy, computer modeling / FEA and DOE. Interface with and aided development of technology partnership with Dupont.

Staff Engineer, R+D Coatings and Adhesives

Patented coatings for protection and lubricity of $200 million in balloon angioplasty catheters. With manufacturing, developed UV cure adhesive for PE/PET. Plant Silicone contamination identified and corrected.

Permuthane Division ICI/Zeneca- Peabody, MA

Technical Marketing Manager, Coating/Adhesives Application

Division staff position with $500,000 budget required development of polymers and custom formulation of coatings in automotive, textile, recreational, industrial, adhesive and construction markets. Field marketing and trials, customer presentation and sales training, plant scale-up, recruiting and training 6 professional and 5 technicians for a complex line of coatings and adhesives.

American Medical Optics division AHSC (now Allergan) - Anasco, PR

Chemical Engineer, Production Supervisor

Plant startup and 300% expansion of facility to produce extended wear hydrophilic contact lens polymer. Licensed chemist, initial regulatory compliance and quality control, plant safety chairperson, hired and supervised 21 Spanish-speaking employees.

Zeneca Resins Division of ICI - Wilmington, MA

Technical Service and Synthesis for the company's line of urethane and acrylic resins. Plant strike duty as reactor operator making water and solvent based urethanes.

Educati n

MS Polymer Chemistry, University of Lowell

BS Chemistry, Lowell Technological Institute

Patents and Publicationss

MS Thesis- Polymerization within Liquid Crystalline Media 1978
J. Coatings Tech A three part study of the Corrosion Protection of Steel - NESCT Tech Committee
No. 53, 683.27, 1981
No. 54, 1982
No. 55, 1983.
J. Coated Fabrics 16, p 159 1987 Comply or Defy
SurfACTS in Biomaterials 4 issue2 1999 Organo-Selenium Covalently Attached for Blocking Biofilm
Gene therapy 2003 transgene delivery of plasmid DNA to smooth muscle cells and macrophages from a biostable polymer coated stent
US Patent 5,026,607 Protective, Lubricious Coatings for Medical Devices 1991
US Patent 5,272,012 Protective, Lubricious Coatings for Medical Devices 1993
US Patent 5,599,576 Medical Apparatus Scratch Resistant Coating/ Method Making Same1997
US Patent 5,766,158 Medical Apparatus Scratch Resistant Coating / Method Making Same 1998
US Patent 5,776,611 Crosslinked Hydrogel Coatings 1998
US Patent 6,238,799 Hydrophilic Coating 2001
US Patent Pending Proprietary Hydrophilic Coating
US Patent 6096726 Sustained release of bioactive materials 2000
US Patent office NOA for Sustained release multi- step waterbased coating 2003
US Patent Pending Sustained release one-step coating

Affiliations

Surfaces In Biomaterials Supporting Member
Session Chair and moderator Drug/Gene Delivery 2000, 2001 and 2002
Secretary 2001-2
Society for Biomaterials
Session Chair and reviewer Drug delivery sessions 2002 and 2003
Federation of Societies for Coatings Technology - Tech Committee Chair 1988- 1991
Program Chair for 1988 Coatings Tech Expo, Moderator Coatings Tech Expo 1993
American Chemical Society
Society for Plastics Engineers
Previous Affiliation with the Adhesives and Sealants Council, IFAI and CFFA
Who's Who in Plastics and Polymers 1st Edition Technomic Publishing 1999

EXHIBIT 2

INTERNATIONAL SPECIALTY PR DUCTS

PO Box 1006 Bound Brook NJ 08805

Tel: (908) 271 0111
Tel: 1 800 622 4423

ISP

Polymer ACP-1033

TENTATIVE SALES SPECIFICATIONS

Chemical Description:

Intermediate molecular weight Vinylpyrrolidone/Acrylic acid copolymer

Specifications:

Appearance @25 °C:	Fine white pouder
Relative Viscosity: (1% solids w/v solution in 0.25N NaOH/0.20N LiNO	1.4 - 1.7
Acid Number:	170 - 210
% Moisture: (Karl Fischer)	3.0 Maximum
Solubility: (5% solids in 2% NaOH soln)	Soluble and clear
GC Analysis (MP-614W)	
% Heptane:	1.0 Maximum,
% Vinyl Pyrrolidone:	0.10 Maximum
% Acrylic Acid:	0.20 Maximum

ESSB